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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,497	09/28/2001	Harry S. Sowden	MCP-294	5321

27777 7590 12/15/2004

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EXAMINER	
ORTIZ, ANGELA Y	

ART UNIT	PAPER NUMBER
1732	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/966,497	SOWDEN ET AL.
	Examiner	Art Unit
	Angela Ortiz	1732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 137* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 137* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 October 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04 October 2004 has been entered.

Claim Objections

Claim 1 is objected to because of the following informalities: in claim 1, line 6 repeats information from line 5, and makes the claim unclear, by limiting the cavity instead of the flowable material as it may have been intended. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1-22 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of the term "per se" is unclear and a definition or support cannot be found in the instant specification.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 6-10, 137 are rejected under 35 U.S.C. 102(b) as being anticipated by Dong et al., USP 5,830,502.

The cited reference teaches the claimed process of manufacturing an injection molded dosage form. The detailed method steps include providing a flowable material by first preparing a composition for injection molding, forming the composition into pellets and loading the pellets into an injection molding machine. The injection molding machine conventionally includes a mold cavity, injection nozzle, and heating and cooling means. The composition for the dosage form may comprise a medicament. The molding machine heats the pellets to produce a flowable material, and the material is injected into a mold cavity until the mold is filled, and the composition is solidified into the shape of the cavity. Please see the abstract, col. 3, lines 45-65; col. 4, lines 3-30; col. 5, line 3, col. 6, lines 15-20, 35; col. 7, line 1.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 6-10, 13, 137 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosenberg et al., USP 6,737,005.

The cited reference teaches the claimed process of manufacturing a molded dosage form. The detailed method steps include providing a flowable material by first preparing a composition containing a medicament for shaping by conventional means, such as extrusion which is readable on injecting a flowable material through a nozzle, forming the composition by injecting the material into a mold cavity of a molding roll apparatus. The molding machine shapes the flowable material until the composition is solidified into the shape of the cavity. It is later cooled and solidified. Please see the abstract, col. 2, lines 1-15; col. 3, lines 5-30, 45-65. Claim 2, see col. 3, lines 6-7; claim 137, see col. 3, lines 13-15; claim 6, see col. 4, line18; claim 7, see col. 4, lines 50-55; claim 8, see col. 4, line 61 and claim 9, see col. 4, line 65. to the degree that gelatin is soluble and swellable, see col. 3, lines 64-65.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-13, 21, 137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dong et al., USP 5,830,502.

The cited reference substantially teaches the basic claimed process of manufacturing an injection molded dosage form. The detailed method steps include providing a flowable material by first preparing a composition for injection molding, forming the composition into pellets and loading the pellets into an injection molding machine. The injection molding machine conventionally includes a mold cavity, injection nozzle, and heating and cooling means. The composition for the dosage form may comprise a medicament. The molding machine heats the pellets to produce a flowable material, and the material is injected into a mold cavity until the mold is filled, and the composition is solidified into the shape of the cavity. Please see the abstract, col. 3, lines 45-65; col. 4, lines 3-30; col. 5, line 3, col. 6, lines 15-20, 35; col. 7, line 1.

The cited reference does not teach cooling in the hardening step as claimed.

Note that the hot liquid of the melted pellets is around 100°C, and is injected into a 75°C mold cavity and by injecting hot material into a cooler mold, cooling is being performed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the step of cooling during hardening to solidify the melted material.

With respect to claims 2-5, 11, note that the heating and cooling performed includes conventional means; it would have been obvious to further include the conventional means claimed for achieving the desired temperature effect.

With respect to claims 12-13, see col. 4, lines 18-25; col. 2, lines 35-65, wherein a defect free product is a long-standing object in the art of making dosage forms.

Claims 14-20, 22, 137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dong et al., USP 5,830,502 in view of Voss, USP 6,177,125 for the reasons cited in the previous office action.

The cited primary reference substantially teaches the basic claimed process of manufacturing an injection molded dosage form. The detailed method steps include providing a flowable material by first preparing a composition for injection molding, forming the composition into pellets and loading the pellets into an injection molding machine. The injection molding machine conventionally includes a mold cavity, injection nozzle, and heating and cooling means. The composition for the dosage form may comprise a medicament. The molding machine heats the pellets to produce a flowable material, and the material is injected into a mold cavity until the mold is filled, and the composition is solidified into the shape of the cavity. Please see the abstract, col. 3, lines 45-65; col. 4, lines 3-30; col. 5, line 3, col. 6, lines 15-20, 35; col. 7, line 1.

The cited primary reference does not teach the claimed step of placing an insert in the mold cavity prior to injecting.

The added reference teaches as conventional a method of making coated tablets that comprise a core, the method further including placing the core or insert in the mold cavity prior to complete molding of the tablet. The detailed steps include providing a coating composition in granulate form, adding a core to the granules and molding the composition into tablet form. One embodiment forms the process in a single step, while additional embodiments partially fill the mold, place the core within the mold and then

completely fill the mold to form a coated tablet. Note that the core can be injected. See claims 1-21, col. 1, lines 48-57.

It would to add an insert prior to complete molding of the dosage form, in view of the added reference, when performing the process set forth in the primary reference, for forming an encapsulated tablet. Note that the primary reference prefers a liquid center fill; it would have been obvious to use a non-liquid fill in view of the added reference, for forming an encapsulated tablet in a single process step.

Response to Arguments

Applicant's arguments filed 04 October 2004 have been fully considered but they are not persuasive.

Applicant argues that the newly amended claims differ from the applied prior art reference to Dong et al in that the newly amended claims are drawn to a dosage form per se and not a combination of molded housing into which active ingredients are subsequently introduced. However, by broadening the claims by including "per se", these claims are readable on a formed housing with a molded medicament inserted into the housing, which applicants argue is not claimed. In other words, as the claims now read, the method may be drawn to making a dosage form "by, of, or in itself" containing a first medicament, and is therefore readable on a medicament placed in the dosage form. It is not limited to a monolithic form, or a solid tablet. The Dong reference also includes liquid delivery forms, and while such dosage forms are a composite, the forms are still deemed integral forms. Note that the membrane or the compositions are

injection molded into dosage forms, see col. 3, lines 5-10. With respect to the argued limitation of the medicament being in the flowable material, see col. 7, lines 40-55, wherein the reference teaches that the compositions comprising a therapeutic agent are made by standard manufacturing techniques and includes mixing and pressing into a solid or semisolid shape. Note that claim 13 is not included in the 102 rejection.

With respect to the materials as claimed, note that col. 3, lines 6-11 teach that the dosage forms are injection molded from a mixture of thermoplastic polymers including polymers (claim 6) at col. 3, line 63; glycerine at col. 3, line 19 and polyethylene glycol (wax, claim 10) at col. 3, line 61.

Note also the newly applied art rejection meets the argued limitations and the newly claimed features.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Ortiz whose telephone number is 571-272-1206. The examiner can normally be reached on Monday-Thursday 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on 571-272-1196. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Angela Ortiz
Primary Examiner
Art Unit 1732

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